

P A T E N T

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

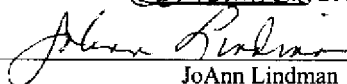
Application No.: 10/616,622 Confirmation No.: 3366
Applicant : Daniel M. Lafontaine
Filed : July 10, 2003
TC/A.U. : 3734
Examiner : Diane D. Yabut
Title : SYSTEM FOR CLOSING AN OPENING IN A BODY CAVITY
Docket No. : 1001.2207101
Customer No. : 28075

PRE-APPEAL BRIEF REQUEST FOR REVIEW

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Commissioner for Patents
PO Box 1450
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By _____


JoAnn Lindman

Dear Sir:

Appellants respectfully request a Pre-Appeal Brief Review of the pending application. A Notice of Appeal is filed herewith.

Please consider this a PETITION FOR EXTENSION OF TIME for a sufficient number of months to enter these papers, if appropriate. Please charge any additional fees or credit overpayment to Deposit Account No. 50-0413.

Appellants have received and carefully reviewed the Final Office Action dated May 23, 2008 and the Advisory Action dated August 1, 2008. Claims 1-14, 16-29, and 31-41 are pending, of which claims 11, 12, and 14 were previously withdrawn from consideration. Claims 1-10, 13, 16-29, and 31-41 have been rejected by the Examiner. This appeal is being filed based on the claim set presented in the Response dated February 21, 2008. Appellants hereby request a Pre-Appeal Conference and file this Pre-

Appeal Conference Brief concurrently with a Notice of Appeal. Favorable consideration of the claims is respectfully requested.

Claims 1-10, 13, 16-20, 24-29, and 31-41 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Lafontaine et al. (U.S. Patent No. 5,964,782 – hereinafter *Lafontaine* '782) in view of Linden et al. (U.S. Patent No. 6,270,515 – hereinafter *Linden*). Appellants respectfully traverse the rejection.

*** “All words in a claim must be considered in judging the patentability of that claim against the prior art.” *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970).” (MPEP 2143.03).

Regarding independent claims 1, 26, and 33: on page 3 of the Final Office Action, the Examiner admits:

“Lafontaine discloses the claimed device *except* for the backing having a generally conical shape with a center portion of the backing distally spaced from a periphery of the backing, and the backing center portion being collapsed proximally toward the backing periphery to have a generally disc shape, and manipulating a collapse actuator releasably coupled to the collapsible pile backing or closure component and operable to move the distal end of the collapsible backing under to a more proximal position under proximally directed force from the non-collapsed position to the collapsed position, and disconnecting the collapse actuator from the collapsible pile backing.” (*italicized* emphasis in original, underlined emphasis added).

The Examiner relies upon *Linden* to provide *Lafontaine* '782 with a collapse actuator “operable to move the distal end of the collapsible backing under to a more proximal position under proximally directed force from a non-collapsed position or generally conical shape to a collapsed position or disc-shape”. However, the Examiner appears to have mischaracterized the art, as the Examiner’s interpretation appears to be only partially correct. The device disclosed by *Linden* and shown in Figures 17-20 may appear to show a mesh sleeve that has the distal end actuated to a more proximal position, as asserted by the Examiner. Nevertheless, the Examiner does not appear to have considered the orientation of *Linden*’s conical shaped backing in her interpretation. The claim language clearly calls for “the backing having a generally conical shape with a center portion of the backing distally spaced from a periphery of the backing...the

backing center portion is collapsed proximally” (emphasis added) – i.e. the tip of the cone is distal of the base of the cone such that when it is actuated, the center portion (tip) of the conical backing is collapsed (pulled) proximally toward the periphery (base).

The device disclosed by *Linden* appears to be configured in the opposite orientation, with the tip of the cone (near 522) located proximal of the periphery/base (514), and the base being moved radially outward and proximally toward the tip under radial expansion of the conically shaped balloon (524). It would appear to be more accurate to say that *Linden* flares the distal end of the conical backing outward, rather than collapses the conical backing proximally to a disc, as asserted by the Examiner. Regardless, the mesh disclosed by *Linden* does not have a center portion of the backing distally spaced from the periphery, nor does the center portion collapse proximally. Therefore, it appears that both *Lafontaine* ‘782 and *Linden* are missing at least these two elements of the claimed invention.

“If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959)” (MPEP 2143.01 VI.)

In addition to the clearly missing elements discussed above, modification of the *Linden* device to put the center of the mesh distally of the periphery would appear to significantly change the principle of operation of the device and would also appear to require significant redesign in order to function. For example, balloon 524 still would not appear to be able to collapse the center of the mesh proximally under radial expansion of the balloon without using a significantly larger and differently shaped balloon, and changing the placement of the mesh on the balloon for deployment. This presents its own challenges, as a larger balloon could create an obstruction, something that is typically undesirable within the heart (the *Linden* device is intended to repair defects in the septal tissue of the heart).

Accordingly, for at least the reasons that the cited combination does not appear to disclose all elements of the claimed invention as recited in independent claims 1, 26, and 33, and that modification of the cited references to achieve the claimed invention would change the principle of operation of the references, Appellants assert that these claims are

indeed patentable over *Lafontaine* '782 in view of *Linden*. Furthermore, since claims 2-10, 13, 16-20, 24-25, 27-29, 31-32, and 34-41 all depend from claims 1, 26, or 33, and add additional elements thereto, Appellants submit that these claims are also patentable over the cited combination. Withdrawal of the rejection is respectfully requested.

Claim 17-23 stand rejected under 35 U.S.C. §103(a) as being unpatentable over *Lafontaine* '782 in view of *Linden*, as applied to claim 16, and further in view of *Redmond* et al. (U.S. Patent No. 6,334,865 – hereinafter *Redmond*). Appellants respectfully traverse the rejection.

As discussed above, *Lafontaine* '782 and *Linden* (either alone or in combination) do not appear to disclose all elements of independent claim 1. *Redmond* does not appear to provide those missing elements. Since claims 17-23 all depend from claim 1 which the Appellants submit is allowable, and add additional elements thereto, Appellants submit that claims 17-23 are also patentable over the cited combination and respectfully request that the rejection be withdrawn.

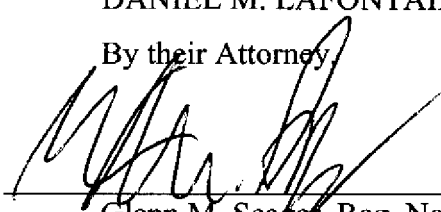
Reexamination and reconsideration are respectfully requested. It is respectfully submitted that the claims are now in condition for allowance. Issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

DANIEL M. LAFONTAINE ET AL.

By their Attorney,

Date: Sept 30, 2009



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